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U.S. DISTRICT COURT
N.D. OF ALABAMA

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

HOSPICE COMPLETE, INC.	]	
	]	
Plaintiff,	]	
	]	
v.	]	
	]	**CV-09-BE-2398-S**
KATHLEEN SEBELIUS,	]	**CV-09-BE-2399-S**
	]	
Defendant	]	
	]	
	]	

AMENDED MEMORANDUM OPINION *NUNC PRO TUNC*

The court enters the following Memorandum Opinion *nunc pro tunc* to replace the Memorandum Opinion (doc. 43) entered on March 30, 2011 through a clerical error of filing a preliminary draft instead of the final version of this Memorandum Opinion.

This consolidated case presents the same issue raised by dozens of hospice providers around the country challenging the legality of 42 C.F.R. § 418.309(b)(1), a regulation promulgated by the Secretary of the U.S. Department of Health and Human Services ("the Regulation"). The Regulation seeks to implement a method of calculating a hospice provider's annual aggregate cap for reimbursement purposes under 42 U.S.C. § 1395f(1)(2). For the reasons stated below, this court joins the Fifth Circuit[1] and the unanimous group of district courts finding that 42 C.F.R. § 418.309(b)(1) is invalid because it directly contradicts the unambiguous

[1] *Lion Health Servs., Inc. v. Sebelius,* ___ F.3d ___, 2011 WL 834018, at 8 (5th Cir. Mar. 11, 2011).

language of the statute it purports to implement.

This matter is before the court on "Plaintiff's Motion for Judgment on the Merits and Memorandum Brief in Support" (doc. 15 in 2398; doc. 14 in 2399[2]), which has been thoroughly briefed. The court finds that the motion for judgment on the merits is due to be granted in part. More specifically, the court finds: (1) that it lacks jurisdiction over both the original and revised determination of the cap for fiscal year 2006; (2) that Hospice Complete has standing to bring the challenge to the validity of the Regulation based on the determination for fiscal year 2007; and (3) that the motion for judgment on the merits is due to be granted as to the determination for fiscal year 2007, because the Regulation used to calculate that determination is invalid. By simultaneous order, the court will permanently enjoin the Secretary from enforcing against Hospice Complete any refund determinations calculated using the Regulation, and further, from using the Regulation to calculate Hospice Complete's aggregate cap amount for any past, present, or future accounting year.

I. BACKGROUND

Medicare Hospice Benefits Program and the HHS Regulation at Issue

In 1982, Congress expanded the scope of benefits available under Medicare to include coverage for hospice care for terminally ill patients. *See* Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. 97-248, § 122, 96 Stat. 356, 364. Under the hospice care benefit, Medicare reimburses a hospice provider a predetermined fee for each day that an eligible patient receives hospice care in the provider's program. 42 U.S.C. § 1395f(i); 42 C.F.R. § 418.302. The

[2]For simplicity's sake, the court will refer to filed documents by number as reflected in the lead case, 09-2398.

Medicare statute now allows each individual hospice *patient* to receive hospice benefits for a theoretically unlimited period of time as long as the patient remains certified as terminally ill with a life expectancy of less than six months. *See* 42 U.S.C. §§ 1395f(a)(7) and 1395x(dd)(3)(A). However, the statute establishes a *cap* on total reimbursement payments per medicare beneficiary that a hospice *provider* may receive in a fiscal year. *Id.* § 1395f(i)(2). Thus, pursuant to this statute, any hospice provider whose revenues from HHS exceed the cap are subject to demands by HHS for refund.

The relevant statute provides:

> 2(A) The amount of payment made under this part for hospice care provided by (or under arrangements made by) a hospice program for an accounting year may not exceed the "cap amount" for the year (computed under subparagraph (B)) multiplied by the number of medicare beneficiaries in the hospice program in that year (determined under subparagraph (C)).
>
> * * *
>
> (C) For purposes of subparagraph (A), the "number of medicare beneficiaries" in a hospice program in an accounting year is equal to the number of individuals who have made an election under subsection (d) of this section with respect to the hospice program and have been provided hospice care by (or under arrangements made by) the hospice program under this part in the accounting year, *such number reduced to reflect the proportion of hospice care that each such individual was provided in a previous or subsequent accounting year* or under a plan of care established by another hospice program.

42 U.S.C. § 1395f(i)(2) (emphasis supplied).

In 1983, to implement the statute, HHS issued the Regulation challenged in this action. The Regulation reads:

> The hospice cap amount is calculated using the following procedures:
> * * *
> (b) Each hospice's cap amount is calculated ... by multiplying the adjusted cap amount determined in paragraph (a) of this section by the number of Medicare

> beneficiaries who elected to receive hospice care from that hospice during the cap period. For purposes of this calculation, the number of Medicare beneficiaries includes -
>
> > (1) Those Medicare beneficiaries who have not previously been included in the calculation of any hospice cap and who have filed an election to receive hospice care, in accordance with § 418.24, from the hospice during the period beginning on September 28 (35 days before the beginning of the cap period) and ending on September 27 (35 days before the end of the cap period).
> > (2) In the case in which a beneficiary has elected to receive care from more than one hospice, each hospice includes in its number of Medicare beneficiaries only that fraction which represents the portion of a patient's total stay in all hospices that was spent in that hospice. . . .

42 C.F.R. § 418.309(b)(1); *see also* Medicare Program, Hospice Care, 48 Fed. Reg. 38,146-01 (August 22, 1983). The September 27 cut-off date was based on data supposedly showing that the average length of days under hospice care was 70 days[3]; because the accounting year ends October 31, Medicare would count beneficiaries who receive hospice care beginning on or before September 27 in that fiscal year, but would count beneficiaries who receive hospice care beginning on or after September 28 in the subsequent fiscal year. The Regulation at § 418.309(b)(1) has been in place since 1983.

When issuing the *proposal* for this Regulation, HHS provided the following explanation of hospice cap calculations, in the notes to the proposal:

> 7. Hospice Cap
> * * *
> e. Number of Hospice Beneficiaries
> * * *
> The statute specifies that the number of Medicare patients used in the calculation is to be adjusted to reflect the portion of care provided in a previous or subsequent reporting year or in another hospice. With respect to

[3] In her brief, the Secretary acknowledges that the average length of stay in hospice care nationwide was 73 days in 2006 and 71 days in 2008. This data is reported on the CMS website at www.cms.hhs.gov/center/hospice ("Medicare Hospice Data Trends: 1998-2008).

> the adjustment necessary to account for situations in which a beneficiary's election overlaps two accounting periods, we are proposing to count each beneficiary only in the reporting year in which the preponderance of the hospice care would be expected to be furnished rather than attempting to perform a proportional adjustment. *Although section 1814(i)(2)(C) of the Act specifies that the cap amount is to be adjusted "to reflect the proportional adjustment of hospice care that each such individual was provided in a previous or subsequent accounting year * * *", such an adjustment would be difficult* in that the proportion of the hospice stay occurring in any given year would not be known until the patient died or exhausted his or her hospice benefits. We believe that the proposed alternative of counting the beneficiary in the reporting period where the beneficiary used most of the days of covered hospice care will achieve the intent of the statute without being burdensome.
> * * *
> *When a beneficiary elects to receive hospice benefits from two different hospices, we are proposing a proportional application of the cap amount. . . .*

(Doc. 19-3, at 26, quoting from 48 FR 38146-01, at 25) (emphasis supplied).

In its recent *Lion Health* decision, the Fifth Circuit explained how calculations made under the Regulation work:

> Thus, the Regulation deals with patients whose hospice stay extends into more than one fiscal year by using a single-year allocation method – allocating each individual patient cap amount to a single fiscal year based upon the date on which the patient elect for hospice care – rather than a proportional allocation method. A proportional method would allocate each individual patient cap amount to different fiscal years based on the exact proportion of care received by a patient in each relevant fiscal year. Under the Regulation's single year approach, a patient who elects to receive hospice care on or before September 27, 2005, would be counted as receiving care only in FY05, even if the patient continues to receive hospice care in FY06. A patient who elects to receive hospice care on September 28, 2005, however, would be counted as receiving care only in FY06, even though she may have started receiving hospice care in FY05.
>
> A hospice-care provider's Medicare bills are calculated and paid by a Medicare contractor called a "fiscal intermediary" shortly after the provider submits them. *See* 42 U.S.C. § 1395g(a); *see also* 42 C.F.R. §§ 413.64(b) and 418.302(d)-(e). Then, at the close of each fiscal year, the intermediary uses the Regulation to calculate a hospice care provider's

> aggregate cap amount for that fiscal year. *See* 42 C.F.R. § 418.308(c). If a provider's total reimbursement payments received from the intermediary over the course of the fiscal year exceed its aggregate cap amount for that year, the intermediary demands that the provider refund the amount of the overpayments to Medicare. *See id.* § 418.308(d).

Lion Health, 2011 WL 834018, at 2-3.

If a hospice provider disagrees with the Medicare hospice cap refund demand that it receives for a fiscal year, the provider may ask for administrative review, appealing that determination to the Provider Reimbursement Review Board ("PRRB"). 42 C.F.R. §§ 418.311, 405.1803(a)(3). A provider must file an appeal with the PRRB within 180 days of receipt of the notice of determination. 42 U.S.C. § 1395oo(a)(3); 42 C.F. R. § 405.1311(a)(3)(I). When a provider challenges the validity of the Regulation itself, the PRRB lacks the authority to decide that issue or to declare a regulation invalid. *See Bethesda Hosp. Ass'n v. Bowen*, 485 U.S. 399, 406 (1988) (stating "[n]either the fiscal intermediary nor the [PRRB] has authority to declare regulations invalid."). A provider who files an appeal may request that the PRRB determine whether the PRRB has authority to decide "a question of law or regulations." 42 U.S.C. § 1395oo(f)(1); 42 C.F.R. § 405.1842.

The Medicare statute allows for expedited judicial review ("EJR") of cases where the PRRB determines that it lacks authority to decide a question presented in a provider's appeal. The statute provides:

> Providers shall also have the right to obtain judicial review of any action of the fiscal intermediary *which involves a question of law or regulations relevant to the matters in controversy* whenever the Board determines (on its own motion or at the request of a provider of services as described in the following sentence) that it is without authority to decide the question, by a civil action commenced within sixty days of the date on which notification of such determination is received. . . .The Board shall render

> such determination in writing within thirty days after the Board receives the request and such accompanying documents and materials, and the determination shall be considered a final decision and not subject to review by the Secretary. . . .

42 U.S.C. § 1395oo(f)(1) (emphasis added).

History of this Action

Plaintiff, Hospice Complete, Inc[4], is a Medicare certified hospice provider in Birmingham, Alabama.

Fiscal Year 2006

On October 17, 2007, Medicare[5] made a refund demand against Hospice Complete in the amount of $820,490 based upon its calculations for the 2006 fiscal year. Hospice Complete asked for and received approval for an extended repayment plan (ERP), requiring it to repay the alleged overage in monthly installments of $22,167 over the course of 45 months. Hospice Complete has continuously made payments in accordance with this plan.

On March 4, 2009, Medicare gave Hospice Complete a revised demand for a refund based upon a review of calculations for the 2006 fiscal year, determining that the revised cap amount for fiscal year 2006 required Hospice Complete to pay an additional $21,913.00. On or around April 21, 2009, Hospice Complete requested and received approval for an ERP to pay additional monthly installments of $1,914.85 over the course of eleven months. Hospice Complete has continuously made payments in accordance with this ERP.

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[4]As of January 6, 2011, Hospice Complete, Inc.'s name was legally changed to HC Healthcare, Inc. The cap demands from which this appeal arises were directed to Hospice Complete, Inc., and the court will continue to use the Hospice Complete name for consistency.

[5] Although the court understands that the HHS works through a fiscal intermediary, for simplicity's sake the court will refer to that intermediary as "HHS" or "Medicare."

On June 18, 2009, Hospice Complete timely filed an appeal with the Provider Reimbursement Review Board (PRRB) containing issues that are not included in this judicial review. A few months later, or about September 15, 2009, Hospice Complete timely filed a request to revise that appeal to challenge the validity of federal Regulation 42 C.F.R. § 418.309(b)(1), alleging that the revised cap determination for fiscal year 2006 was calculated based on that Regulation. On October 1, 2009, the PRRB notified Hospice Complete of its finding that expedited judicial review is appropriate for the revised fiscal year 2006 refund demand because no material facts are in dispute, the amount in controversy exceeds $10,000, and the PRRB lacks the authority to decide the validity of the Regulation. When the PRRB makes such a ruling, a Medicare provider has 60 days to file a civil action in federal district court. 42 U.S.C. § 1395oo(f)(1). Hospice Complete filed a timely appeal.

Fiscal Year 2007

On March 4, 2009, Medicare made a demand to Hospice Complete for a refund in the amount of $644,366 based on its cap calculations for the fiscal year 2007. Hospice Complete asked for and received approval for an ERP to repay the alleged overage with payments of $14,666.27 per month over the course of 55 months. Hospice Complete has continuously made payments since that time.

On June 18, 2009, Hospice Complete filed an appeal with the PRRB containing issues that are not included in this judicial review, and eventually amended the appeal to add issue that challenged the validity of the Regulation, 42 C.F.R. § 418.309(b)(1), pursuant to which the 2007 fiscal year cap was calculated. On October 1, 2009, the PRRB notified Hospice Complete of its finding that expedited judicial review is appropriate because no material facts are in dispute, the

amount of controversy exceeds $10,000, and the PRRB lacks authority to decide the validity of the Regulation.

Judicial Review

On November 25, 2009, within 60 days of both PRRB rulings, Hospice Complete filed these actions against the Secretary of HHS: CV-09-2398 involving the fiscal year 2007 cap determination and CV-09-2399 involving the revised fiscal year 2006 cap determination. Both actions challenge the validity of 42 C.F.R § 418.309(b)(1) as it was allegedly used to calculate cap liability for Hospice Complete. The distinction between the suits before consolidation was the fiscal year in which the challenged cap liability calculation for Hospice Complete occurred: CV-09-2398 challenges the calculation for fiscal year 2007, and CV-09-2399 challenges the calculation for fiscal year 2006. The Secretary also asserts that a distinction exists between the suits based on which part of Regulation 42 C.F.R § 418.309(b) was used to make the cap calculation. On April 15, 2010, by agreement of the parties, this court ordered that the two suits be consolidated with 09-2398 as the lead case and 09-2399 as the member case.

In June 2010, Hospice Complete filed the motion for judgment on the merits currently before the court.

During the pendency of this action, HHS continued to issue new demands to Hospice Complete's providers for refund of alleged cap overpayments, allegedly relying on the same challenged Regulation: on May 25, 2010, HHS issued a demand to Hospice Complete's Jasper and Trussville providers for alleged cap overpayments for fiscal year 2009; and on August 17, 2010, it issued such a demand to the Pelham provider for the same fiscal year.

Hospice Complete filed an emergency motion to stay its obligation to repay HHS for

amounts exceeding the cap limits for fiscal years 2006 and 2007 pending this court's ruling on the merits (doc. 16 as supplemented by doc. 17). The court granted the emergency motion and, entering a temporary injunction to "be in effect pending a judgment on the merits of these consolidated actions," enjoined the Secretary from enforcing the cap refund demands against Hospice Complete for the following: the original and revised fiscal year 2006; fiscal year 2007; fiscal year 2008; fiscal year 2009; "and any demand for repayment based on any present or future accounting year calculated pursuant to 42 C.F.R. § 418.309(b)(1)." (Doc. 25).

On November 19, 2010, Hospice Complete filed with the PRRB a mandatory "Common Issue Related Party" (CIRP) group appeal for the fiscal year 2009 refund demands for its three providers and also filed a request for expedited judicial review of the demands, because the challenge involved a legal question as to the Regulation's validity. On December 16, 2010, the PRRB issued a letter granting the request for EJR, finding that

> 1) [the PRRB] has jurisdiction over the matter for the subject year and the Providers are entitled to a hearing before the Board;
> 2) based upon the Providers' assertions regarding the hospice cap issue, there are no findings of fact for resolution by the Board;
> 3) the Board is bound by the regulation; and
> 4) it is without the authority to decide the legal question of whether the regulation, 42 C.F.R. § 418.309(b)(1), is valid.

(Doc. 32-4, at 3). On January 12, 2011, HHS notified Hospice Complete that the Administrator, Centers for Medicare & Medicaid Servises (CMS), on its own motion, would be reviewing the PRRB's decision regarding Hospice Complete's hearing request and request for EJR.

In February of 2011, Hospice Complete filed a motion requesting leave to amend the complaint to include cap period refund determinations involving its Jasper, Trussville, and Pelham providers for fiscal year 2009, asserting that those demands involve the identical parties

and legal issues as the instant case. (Doc. 36). The court granted that motion (doc. 39), but its order stated that granting leave to amend would not affect the then-pending motion for judgment on the merits as to claims for fiscal years 2006 and 2007. On March 21, 2011, Hospice Complete filed an amended complaint adding the claims involving the fiscal year 2009 cap refund determinations. (Doc. 42).

II. Standard of Review

As this case arises under the Medicare statute, 42 U.S.C. § 1395oo(f)(1), judicial review is guided by "the applicable provisions under chapter 7 of Title 5," the Administrative Procedure Act, 5 U.S.C. § 701 *et. seq.* 42 U.S.C. § 1395oo(f)(1). In such cases, the court's review is confined to the administrative record that the agency compiles. *See, e.g., Washington v. Office of the Comptroller of the Currency*, 856 F.2d 1507, 1511 (11th Cir. 1988) (citing *Camp v. Pitts*, 411 U.S. 138, 142 (1973)). A reviewing court must affirm the agency's decision unless it determines that the decision was "arbitrary, capricious, an abuse of discretion or otherwise not in accordance with the law," 5 U.S.C. § 706(2)(A), or was "unsupported by substantial evidence," 5 U.S.C. § 706(2)(E). The "arbitrary and capricious" standard is very similar to a "reasonableness" standard. *See Marsh v. Oregon Natural Res. Council*, 490 U.S. 360, 377 n. 23 (1989). Deference to the Secretary's interpretation of complex and highly technical regulatory programs, such as Medicare, is especially warranted. *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994).

The issue of the validity of a regulation is a question of law. *See Lion Health,* 2011 WL 834018, at 8. When the court addresses a challenge to the validity of a regulation, the court must give controlling weight to the regulation, promulgated pursuant to an express delegation of

legislative authority, *unless* the court finds it to be arbitrary, capricious, or contrary to statute. *Gregory v. First Title of Am., Inc.,* 555 F.3d 1300, 1302 (2009). In the case of *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, the Supreme Court of the United States articulated the familiar process under which a court should proceed in evaluating such a regulation:

> [The court] is confronted with two questions. First, always, is the question whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress. If, however, the court determines Congress has not directly addressed the precise question at issue, the court does not simply impose its own construction of the statute, as would be necessary in the absence of administrative interpretation. Rather, if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute.

467 U.S. 837, 842-43 (1984).

III. Discussion

Hospice Complete brings this suit challenging cap calculations and resulting refund demands made pursuant to 42 C.F.R. § 418.309(b)(1), which Hospice Complete asserts is an invalid regulation because it contradicts the clearly expressed mandate and intent of Congress set forth in 42 U.S.C. § 1395f(i)(2). The instant motion requests a judgment on the merits regarding cap refund demands made pursuant to that regulation for fiscal years 2006 and 2007.

The Secretary asserts that this court lacks subject matter jurisdiction over this matter, and to the extent that the court reaches the merits of the challenge to the validity of HHS's Regulation, the Secretary argues that the Regulation is a valid and permissible implementation of the Medicare statute.

A. Subject Matter Jurisdiction

The Secretary raises two jurisdictional matters in this action. As to the determination regarding fiscal year 2006, she argues that the court has potential jurisdiction *only* over the revised determination, and because the revised determination was not made pursuant to the challenged Regulation, the court has no jurisdiction over any of the fiscal year 2006 claims. As to the determination of fiscal year 2007, she challenges Hospice Complete's Article III standing as further explained below.

1. Fiscal Year 2006

The initial jurisdictional issue is whether this court lacks subject matter jurisdiction over the challenge to the fiscal year 2006 cap refund determination. Case number 09-CV-2399 arises from the PRRB having granted Hospice Complete's request for expedited judicial review of the *revised* Medicare hospice cap determination for fiscal year 2006. Hospice Complete did not file an appeal within the required 180 days of the *original* fiscal year 2006 refund determination: a cap overpayment refund determination issued on October 17, 2007 for the amount of $820,490.

On March 4, 2009, however, the Medicare program issued a revised Medicare hospice cap determination for the fiscal year 2006. In this revision, the Medicare program adjusted the number of Hospice Complete beneficiaries from 200.7475 to 199.6830 – pursuant to 42 C.F.R. § 418.309(b)(2), *not* the challenged 42 C.F.R. § 418.309(b)(1) – to take into account "fractional beneficiaries" who received hospice care from both Hospice Complete and another hospice provider and to apportion payments accordingly. *See* Doc. 6-1, at 14 & 35 ("Fractional Beneficiary Summary" worksheets for fiscal year 2006 and revised fiscal year 2006 reflecting the change in allowable beneficiaries and showing "% beneficiary belonging to this hospice"). This

revised determination found that Hospice Complete had exceeded the cap by an additional $21,913 beyond the original refund demand of $820,490 for a total 2006 refund liability of $842,403. The notice advising Hospice Complete of this revision stated in relevant part:

> As outlined in 42 CFR 418.309, hospices are subject to a cap on the total Medicare payments made to the agency. The hospice cap amount for the above referenced cap year is $20,585.39. We have completed a *revised* review of the hospice cap amount for your agency for this cap period. As a result of this review, Medicare payments to your agency have exceed the cap amount by $842,403.
>
> Since the original overpayment of $820,490 was determined on October 17, 2007, the total ***additional*** amount due the Medicare program, at this time for the cap year ended 10/31/06 is **$21,913.**
>
> ****
> A copy of our computation is enclosed. . . .

(Doc. 6-1 in 09-2399, at 56 & 58) (emphasis in original). The attached computation included computations titled "Cap on Overall Medicare Reimbursement," listing the following figures:

CAP ON OVERALL MEDICARE REIMBURSEMENT	
1. MEDICARE BENEFICIARIES ELECTING HOSPICE CARE	199.6830
2. STATUTORY CAP AMOUNT FOR THE CAP YEAR ENDED	$20,585.30
3. ALLOWABLE MEDICARE PAYMENTS	$4,110,552.43
4. ACTUAL PAYMENTS PER THE PS&R PAID THROUGH 1/31/09	$4,952,955.72
5. PAYMENTS IN EXCESS OF THE CAP AMOUNT	**($842,403)**
6. PREVIOUS 2006 CAP OVERPAYMENT CALCULATED ON 10/17/07	**$820,490**
7. ADDITIONAL CAP OVERPAYMENT FOR 2006	**($21,913)**

Id. at 59 (emphasis in original). Hospice Complete filed a timely administrative appeal of the *revised* determination.

If the agency had never revised its hospice cap refund demand for fiscal year 2006, then this court would not have jurisdiction to review any part of that refund demand because Hospice Complete did not appeal the original demand. However, HHS did revise that demand, which resulted in the present timely appeal. The threshold issue for this court is the scope of its

jurisdiction on appeal *in light of that revision*. In other words, the issue is whether its jurisdiction encompasses a challenge to Hospice Complete's entire cap determination for fiscal year 2006 or, as the Secretary contends, whether a more limited review must focus only upon the revision pursuant to 42 C.F.R. § 418.309(b)(2) of Hospice Complete fractional beneficiaries. To determine the answer, the court will first look to the relevant Medicare laws and regulations.

After an initial cap determination, a fiscal intermediary may reopen and revise its determination within three years of the original determination. 42 C.F.R. § 405.1885(b). The revision is considered "a separate and distinct determination" from the original determination. 42 C.F.R. § 1889(a). The appeal from the revised demand must be "issue-specific." *See* 42 C.F.R. § 1889 (heading). It only opens the original determination for appeal to the extent that it was "specifically revised":

> (b)(1) Only those matters that are *specifically revised* in a revised determination or decision are within the *scope of any appeal* of the revised determination or decision.
>
> (2) Any matter that is *not specifically revised* (including any matter that was reopened but not revised) *may not be considered* in any appeal of the revised determination or decision.

42. C.F.R. § 1889(b) (emphasis added).

Some courts have addressed this regulation and explained that the issues subject to appeal include only items that were reconsidered or revisited in the revised demand. *See, e.g., HCA Health Servs. of Okla., Inc. v. Shalala,* 27 F.3d 614, 615, 620-21 (D.C. Cir. 1998) ("[A] provider's appeal ... is limited to the specific issues *revisited* on reopening and may not extend further to all determinations underlying the original [demand]." (emphasis added) (that court both revisited and adjusted cost items and declined to decide whether reconsideration without

adjustment sufficed to trigger appeal rights).

The Seventh and Ninth Circuits perhaps have a broader approach to appeal rights, allowing appeal of all matters the fiscal intermediary had *reconsidered* regardless of whether it ultimately *adjusted* them. *Edgewater Hosp., Inc. v. Bowen*, 857 F.2d 1123, 1135 & 137 (7th Cir. 1989) (holding that appeal rights attach to all items "challenged by the provider" and/or reviewed by the intermediary regardless of whether they ended up being altered: "alteration is not a necessary component of a revision or a review."); *French Hosp. Med. Ctr.*, 89 F.3d 1411, 1420 (9th Cir. 1996) (explicitly adopting the Seventh Circuit's approach in *Edgewater*). However, the Ninth Circuit has held that where an aggregate item, such as a schedule of cost limits, is involved in revision, appeal rights extend only to those discrete components of the aggregate item that are reconsidered and not to other components or to the aggregate itself. *French*, 89 F.3d at 1416; *Anaheim Mem'l Hosp. v. Shalala*, 130 F.3d 845, 853 (9th Cir. 1997).

Neither party has pointed this court to controlling decisions addressing this specific issue in the Eleventh Circuit, and the court is aware of none. The Secretary did cite the court to a district court case in this district, *Alacare Home Health Services, Inc. v. Bowen*, which the Eleventh Circuit affirmed in apart and reversed in part; however, that case did not involve an appeal of a revised determination.[6] No. CV-88-PT-163, 1988 WL 235544, *7 (N.D. Ala. Dec. 1, 1988), *aff'd in part and remanded in part sub nom Alacare Home Health Servs., Inc. v. Sullivan*,

[6] In the *Alacare* case, the 1984 Medicare determination was never reopened. Plaintiff(s) mistakenly believed that a particular letter constituted notification of revision and appealed within 180 days from that "revision" but more than 180 days of the unrevised determination. The court ultimately concluded that it lacked jurisdiction to address an appeal on that claim because it was untimely, and the Eleventh Circuit affirmed that part of the decision. 891 F.2d at 856. Thus, any discussion in the district court decision regarding the effect of a revised determination was mere *dicta*.

891 F.2d 850 (11th Cir. 1990).

Hospice Care asserts that the revised 2006 hospice cap refund determination "in its entirety" is properly before the court, characterizing the revision as a recalculation of the entire cap amount, not of a discrete component part. The Secretary disagrees, stating that the only item revised and certainly the only one adjusted was the number of allowable fractional beneficiaries – that is, the number of beneficiaries was adjusted to reflect those who received hospice care from both Hospice Complete *and* another hospice care provider and to apportion costs accordingly. Thus, the Secretary argues that the revised determination of fractional beneficiaries is the *only* matter subject to appeal. In support of that assertion, it refers the court to the "Fractional Beneficiary Summary" work papers for the fiscal year 2006 determination – which shows 25.7475 allowable beneficiaries – as compared to those for the revised fiscal year 2006 determination – showing 24.6830 allowable beneficiaries. The difference between the two – 1.0645 – accounts for the difference between the number of beneficiaries in the original fiscal year 2006 determination, 200.7475, and the number of beneficiaries in the revised fiscal year 2006 determination, 199.6830. Thus, the Secretary has established factually – with no evidence presented to dispute it – that the review was limited to one discrete item: apportionment of beneficiaries where more than one hospice provider was involved, resulting in the subtraction of 1.0645 beneficiaries on Hospice Care's account. Significantly, the calculation apportioning fractional beneficiaries among multiple hospice care providers is not made pursuant to 42 C.F.R. § 418.309(*b)(1)* – the Regulation challenged here – but rather, is made pursuant to 42 C.F.R. § 418.309*(b)(2)*:

> (2) In the case in which a beneficiary has elected to receive care from more than one hospice, each hospice includes in its number of Medicare beneficiaries only that fraction which represents the portion of a patient's total stay in all hospices that was spent in that hospice. . . .

Hospice Complete does not challenge that part of the regulation in this suit.

Hospice Complete proffers the decision in the case of *Zia Hospice v. Sebelius*, currently pending in the district of New Mexico, as supporting its argument that a revision of the cap amount renders the entire cap determination subject to appeal even absent an appeal of the original determination. 723 F. Supp. 2d 1347 (D.N.M. 2010). The court finds the *Zia* case distinguishable from the instant case. In *Zia*, the evidence did not reflect that the Secretary only reconsidered and adjusted a specific, discrete component of the cap determination. Further, the evidence in *Zia* did not reflect that the Secretary's review only involved recalculations made pursuant to a regulation that was not challenged. Therefore, the court finds the *Zia* decision to be inapposite.

The court finds that under *any* of the reasonable statutory interpretations of the scope of appeal rights discussed above, the scope of appeal for fiscal year 2006 is limited to the revision of fractional beneficiaries issued in October of 2007. The only matter "specifically revised" was a discrete one: the apportionment of beneficiaries of multiple hospice care facilities, a determination made pursuant to 42 C.F.R. § 418.309(b)(2). That regulation is not challenged in this litigation. Hospice Complete's request for expedited judicial appeal (doc. 6-1, at 5-8 in CV-09-1889) challenges only the validity of 42 C.F.R. § 418.309(b)(1) and the accuracy of cap refund demand calculations applying that invalid Regulation; the PRRB's grant of that appeal request is expressly based upon the challenge to 42 C.F.R. § 418.309(b)(1) (doc. 6-1 at 4-5 in

CV-09-1889); and further, the Complaint itself challenges the validity of 42 C.F.R. § 418.309(b)(1) but not the (b)(2) part of that regulation. (Doc. 1 in CV-09-2399, at 12). Because Hospice Complete raises no other grounds for appeal, the court finds that the agency's decision as to the revised fiscal year 2006 determination is not properly before this court and is due to be dismissed. To the extent that this finding means that Hospice Complete has failed to meet the jurisdictional requirements of a Medicare-related appeal, the court dismisses the claims involving the revised determination for fiscal year 2006, based upon a lack of jurisdiction. [7]

Given the court's ruling regarding the scope of this appeal, the original fiscal year 2006 determination is not before this court because Hospice Complete did not effect a timely appeal of that determination. To the extent that this action purports to include that determination, the court finds that it is without jurisdiction to address it. Therefore, the claims based on the original and revised fiscal year 2006 determinations, originally filed as Case No. 09-CV-02399, are due to be dismissed for lack of jurisdiction. The court notes that on July 13, 2010, it entered a temporary injunction in this action (doc. 25) enjoining "The Secretary, or any person or entity acting on her behalf from enforcing the following cap refund demands against Hospice Complete: the Original Fiscal Year 2006 Demand; the Revised Fiscal Year 2006 Demand . . . . . This temporary injunction will be in effect pending a judgment on the merits of these consolidated actions." The

[7] As clear as this jurisdictional matter is, the court is troubled by the incomplete nature of the information communicated to Hospice Complete in the October revised notice as to the fiscal year 2006 determination. In the future, if the Secretary conducts a limited, discrete revision and desires to limit appeal to that discrete revision, then she should ensure that her fiscal intermediary does a better job communicating the nature of the revision and the specific regulations involved. Better communication will enure to the benefit of all parties; not only would it ensure that the hospice provider can make an informed decision about appeal, but also it may avoid expensive, unnecessary appeals.

accompanying order of judgment and permanent injunction in this case shall operate as an end to the temporary injunction as to the original and revised fiscal year 2006 refund demands.

2. Standing

The Secretary also challenges Hospice Complete's Article III standing to bring an action questioning the validity of Regulation 42 C.F.R. § 418.309(b)(1) and its use in calculating its cap refund determination for fiscal year 2007. As the party invoking federal jurisdiction, Hospice Complete bears the burden of establishing its standing to bring this case. *See Lujan v. Defenders of Wildlife,* 504 U.S. 555, 560-61 (1992). To meet that burden, it must prove all three of the following elements: (1) that it suffered an injury in fact; (2) that a causal connection exists between the injury and the challenged conduct; and (3) that a favorable decision from the court would likely redress its injury. *Id.* at 560.

The Secretary argues that Hospice Complete has failed to establish the standing elements, because it has failed to prove that "its overpayment liability would be any different under any ... methodology [other than the challenged Regulation]," and thus, its "assertions have remained at the level of bare conjecture and hypothesis." (Doc. 22, at 29). Indeed, Hospice Complete has not attempted to demonstrate directly that its cap liability would be lower under the statutory method of calculation; it offers no such calculations. However, it argues that it need not present such proof to establish the elements of Article III standing. Instead, it asserts that it has established standing by offering evidence that HHS calculated Hospice Complete's cap refund demands at issue by applying an invalid Regulation; according to this argument, the application of the invalid Regulation itself confers standing apart from evidence of economic injury.

Because of the number of lawsuits hospice providers have filed throughout the nation

challenging the Regulation in question, this same standing issue has been presented to numerous courts. This court joins other district courts finding that standing exists in circumstances when HHS has applied the challenged Regulation to the hospice provider to calculate cap liability and demands a refund based on those calculations, even in the absence of evidence the cap overpayment amounts would be less if calculated consistently with the Medicare statute. *See, e.g., Affinity Healthcare Servs, Inc. d/b/a Affinity Home Hospice Servs. v. Sebelius,* No. 10-0945-RMU, at 21 n. 12 (D. D.C. decision filed Nov. 30, 2010) (finding that standing exists by virtue of the fact that the hospice provider is directly subjected to an unlawful regulation and rejecting defendant's argument that the hospice provider lacked standing because it did not submit a calculation demonstrating monetary loss); *Autumn Light Hospice v. Sebelius,* 2010 WL 988470, at *3 (W.D. Okla. Mar. 12, 2010) (finding standing because the plaintiff "satisfie[d] the injury in fact requirement because the demand repayment amount [was] based on the allegedly invalid calculations of 42 C.F.R. § 418.309(b)"); *Compassionate Care Hospice v. Sebelius,* No. 5:09-CV-00028, doc. 17, at 4 (W.D. Okla. decision filed June 7, 2010) (doc. 31-1 in the instant case) (summary judgment stage) (finding standing despite the absence of evidence calculating the amount of economic harm where "the administrative record makes clear that the application of the challenged regulation led to the determination of the overpayment")*; Los Angeles Haven Hospice, Inc. v. Sebelius*, No. 2:08-CV-4469, doc. 50, at 5-9; 2009 WL 5868513, at *3-4 (C.D. Cal. July 13, 2009) (doc.19-8, Ex. F in the instant case) (summary judgment stage) (finding standing and stating that the injury question is whether "HHS is operating an invalid regulation . . .not whether Plaintiff's liability is greater under the operation of section 418.309 than it would be under some other regulation"); *Russell-Murray Hospice, Inc.*, No. 09-CV-2033, at 15-16 (D.

D.C. decision filed Nov. 30, 2010) (doc. 31-2 in the instant case) (summary judgment stage) (finding standing - concurring with courts that have found standing based on the application of the challenged Regulation apart from evidence of economic harm, but also finding that the plaintiff "established a substantial probability that the application of the challenged regulation resulted in an increase in the []cap liability"); *Tri-County Hospice, Inc. v. Sebelius,* 2010 WL 784836, at *3 (E.D. Okla. Mar. 8, 2010) (slip copy) (concurring "with those district courts which have found the existence of standing apart from any asserted monetary injury"). In *Lion Health*, the district court applied the same approach, i.e., the mere application of the invalid Regulation caused the injury. When the Secretary challenged on appeal this approach to standing, the Fifth Circuit said that it did not have to reach that basis for standing, because the plaintiff did indeed show financial injury. 2011 WL 834018, at 3-4.

Despite the numerous cap liability cases in which she and her predecessors have questioned the hospice provider's standing, the Secretary points this court to only one decision ultimately rejecting standing on Article III grounds based on the absence of a showing that the use of the statutory calculation would have resulted in a higher cap amount. *See Am. Hospice, Inc. v. Sebelius,* CV 1:08-1879-JEO, doc. 29, at 35-46 (N.D. Ala. January 27, 2010) (finding that the plaintiff failed to establish the redressability element of standing at summary judgment stage where it did not present evidence of a "reasonable probability" that its cap liability would be reduced if calculated according to the statutory method); *see also* the other cases that the Secretary cited: *Heart to Heart Hospice, Inc. v. Leavitt,* No. 1:07-CV-289-M-D, 2009 WL 279099, *6 (N.D. Miss. Feb. 5, 2009)(unpublished) and *Sojourn Care, Inc. v. Leavitt,* No. 07-CV-375-GKF-PJC (N. D. Okla. March 3, 2009) (unpublished) (neither stating expressly that

Article III standing was lacking and neither dismissing the complaint for lack of subject matter jurisdiction - the proper disposition when Article III standing is lacking). Although the *American Hospice* decision is well-reasoned, the court rejects the minority view espoused in it for the reasons explained below.

No dispute exists that HHS applied the challenged Regulation to calculate Hospice Complete's cap refund liability for fiscal year 2007. No dispute exists that HHS has issued demands to Hospice Complete for refund of that liability and that Hospice Complete was repaying that liability with interest up to the point this court entered the temporary injunction. Under those circumstances, this court finds that the injury asserted – the calculation of Hospice Complete's cap liability and cap refund liability pursuant to an allegedly invalid Regulation – is an injury that is "concrete and actual or imminent, not conjectural or hypothetical." *See Steel Co. v. Citizens for a Better Env't,* 523 U.S. 83, 103 (1998) (internal quotations removed).

Because the injury is HHS's application of the invalid Regulation, the element of traceability to the challenged conduct logically follows; the two go hand in hand. Thus, Hospice Complete has established injury in fact and causal connection, the first two elements required to establish standing. As to the element of redressability, the court can declare the Regulation to be invalid and order cap payment and overpayments to be recalculated in accordance with the Medicare statute. *See Compassionate Care Hospice,* doc. 31-2 in the instant case, at 18 & 26 (invalidating the Regulation, prospectively enjoining HHS from applying the Regulation to the plaintiff, and ordering that the case be remanded for re-calculation of the cap amounts); *Hospice of N.M., LLC v. Sebelius*, 691 F. Supp. 2d 1275, 1295 (D.N.M. 2010) (concluding that because the injury suffered was HHS's application to plaintiff of the allegedly invalid Regulation, any

finding that the Regulation was invalid would at least partially redress plaintiff's injury). Therefore, the court finds that Hospice Complete has met the three elements of standing.

This finding comports with guidance from the Supreme Court of the United States in the *Lujan v. Defenders of Wildlife* decision addressing standing in suits challenging the legality of government action. 504 U.S. 555 (1992). In that decision, the Court explained that whether standing exists in such actions "depends considerably upon whether the plaintiff is himself an object of the action (or foregone action) at issue. If he is, there is ordinarily little question that the action or inaction has caused him injury and that a judgment preventing or requiring the action will redress it." *Id*. at 560-61. As noted above, in the instant case, Hospice Complete challenges the validity of the Regulation of 42 C.F.R. § 418.309(b)(1); the government has applied the challenged Regulation to Hospice Complete directly in calculating its cap refund for fiscal year 2007; Hospice Complete is the object of the challenged action; and this court has the authority to enter a judgment preventing the application of the challenged Regulation. Therefore, the court finds Hospice Complete has standing to challenge that action as to the fiscal year 2007 determination.

B. The Merits of Hospice Complete's Challenge to 42 C.F.R. § 418.309(1)

The remaining claim focuses on the cap refund determination for fiscal year 2007 and the remaining issue involving that claim is whether 42 C.F.R. § 418.309(b)(1) is invalid as conflicting with the controlling statute, 42 U.S.C. § 1395f(i)(2)(C). HHS argues that the Regulation is a valid and permissible implementation of the Medicare statute. This court disagrees for the reasons stated below.

The court must give controlling weight to a regulation, such as the one at bar,

promulgated pursuant to an express delegation of legislative authority, *unless* the court finds it to be arbitrary, capricious, or contrary to statute. *See Gregory v. First Title of Am., Inc.,* 555 F.3d 1300, 1302 (2009). In the case of *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, the Supreme Court of the United States articulated the familiar two-step process under which a court should proceed in evaluating such a regulation. 467 U.S. 837, 842-43 (1984). Under that process, the court must first determine "whether Congress has directly spoken to the precise question at issue." *Id.* If the answer to that first question is yes, the inquiry ends and does not proceed to step two of the analysis; when a statute speaks directly and unambiguously to an issue, courts give the statute's language effect and do not defer to the agency's interpretation. *Sierra Club, Inc. v. Leavitt,* 488 F.3d 904, 912 n. 12 (11th Cir. 2007). To determine whether the statute does indeed speak directly to the issue in question, courts employ "traditional tools of statutory construction." *Chevron*, 467 U.S. at 843 n. 9.

Hospice Complete asserts that 42 C.F.R. § 418.309(b)(1) fails at step one of the *Chevron* analysis, because that Regulation conflicts with the intent of Congress, expressed clearly and unambiguously in the controlling statute. The court agrees, and thus, joins the numerous other courts, including the Fifth Circuit, that have addressed the issue and found the statute to be invalid. *See, e.g., Lion Health Servs., Inc. v. Sebelius,* ___ F.3d ___, 2011 WL 834018 (5th Cir. Mar. 11, 2011) (affirming district court as to the finding that the challenged Regulation was unlawful, and reversing as to the district court's finding that the Secretary should refund all payment obligations calculated pursuant to the Regulation; rather, the district court should have remanded the case to the agency for a recalculation); *Affinity Healthcare Servs, Inc. d/b/a Affinity Home Hospice Servs. v. Sebelius,* ___ F. Supp. 2d ____, 2010 WL 4258989 Case No. 1:10-CV-

00946, at 22-26 (D.D.C. Oct. 25, 2010) (doc. 31-6 in the instant case); *American Hospice, Inc. v. Sebelius,* Case No. 1:08-CV-01879, doc. 29, at 58 (N.D. Ala. January 27, 2010); *Compassionate Care v. Sebelius,* Case No. 5:09-CV-0028, at 8-10, 2010 WL 2326216 (W.D. Okla. June 7, 2010) (Slip copy) (doc. 31-1 in the instant case); *Harris Hospice, Inc. v. Sebelius,* No. 10-CV-252 & 10-CV-275, 2011 WL 42894, at *5 (E.D. Tex. 2011); *Hospice of New Mexico v. Sebelius,* Case No. CV-09-00145, doc. 34, at 25- 27 (D.N. M. April 12, 2010) (doc. 19-16, at 26-28 in the instant case); *IHG Healthcare d/b/a Grace Hospice of Texas v. Sebelius,* 717 F. Supp. 2d 696 (S.D. Tex. Magistrate decision filed May 7, 2010; district judge's order adopting the opinion filed June 13, 2010) (docs. 31-3& 31-4 in the instant case); *Legacy Health Care, Inc. v. Sebelius,* Case No. 1:09-CV-149, at 1 (D. Utah Aug. 17, 2010) (doc. 31-5 in the instant case); *Los Angeles Haven Hospice, Inc. v. Sebelius,* Case No. CV-08-4469, doc. 50, at 8-9 (C.D. Cal. July 13, 2009) (doc. 19-8 in the instant case); *Russell-Murray Hospice, Inc. v. Sebelius,* Case No. 1:09-CV-02033, at 22-25 (D.D.C. July 20, 2010) (doc. 31-2 in the instant case); *Tri-County Hospice, Inc. v. Sebelius,* Case No. CV-08-273 & CV-09-407 (Consolidated) doc. 23, at 6 (E.D. Okla. Mar. 8, 2010) (doc. 19-14, at 7) and 2011 WL 227577 (E. D. Okla. Jan. 24, 2011) ("reaffirm[ing] its previous rulings that the regulation is invalid").

As the Fifth Circuit carefully explained in its recent *Lion Health* decision:

> We find that Congress has "spoken directly to the precise question at issue" with the text of § 1395f(i)(2)(C), and that only a proportional calculation method based on each individual patient is permitted by the statute. The text of the statute explicitly refers to "*the proportion* of hospice care that *each such individual* was provided," which cannot be accomplished through a single-year allocation that only seeks proportionality on the aggregate level across several years.

2011 WL 834018, at 5. The Court of Appeals addressed the Secretary's argument – also proffered in this case – that Congress's use of the word "reflect" in the statute created ambiguity and "allowed the Secretary some discretion in determining the best method" to calculate the cap and serve the statute's purpose. (Def.'s Resp. Br., Doc. 22, at 37). In rejecting that argument, the Court explained:

> The statute at issue speaks directly in terms of the proportion of care that *each such individual* was provided. *See* 42 U.S.C. § 1395f(i)(2)(C). A regulation that assigns an individual patient's care to a single year cannot possibly "reflect" the portion of a fiscal year that the individual spent at the hospice. Allocating 100% of an individual patient's cap amount to [one fiscal year] does not "reflect" the proportion of care that patient received when the actual proportion of care received by that patient was 10% in [one fiscal year] and 90% in [the next fiscal year]. Because the statute requires the Secretary to calculate the proportion of care in a fiscal year on an individual level, only a proportional calculation method meets this requirement.

Lion Health, 2011 WL 834018, at 5 (emphasis in original).

The same analysis applies in the instant case. The conflict between the statute and the Regulation occurs in the allocation of cap amounts for patients who may have received care in more than one fiscal year. The statute directs that the provider's number of beneficiaries for a fiscal year must be "reduced to reflect the *proportion* of hospice care that each such individual was provided in a previous or subsequent accounting year." 42 U.S.C. § 1395f(i)(2)(C) (emphasis added).

Because the face of the statute so clearly and unambiguously states Congressional intent as to that allocation, the court need not spend pages analyzing it. This court agrees with the Fifth Circuit and the unanimous group of district courts finding that the Regulation simply fails to follow that clear direction. The Regulation assigns the beneficiary's entire allocation to a single

year, even if the services were provided in different years, based solely on the date of admission to the hospice program, and in clear conflict with the statute.

Having found a clear conflict with the relevant statute, the court, therefore, by the authority the APA provides in 5 U.S.C. § 706, declares that the Regulation 42 C.F.R. § 418.309(b)(1) is facially invalid, unlawful, and should not be enforced; that the agency's action in *issuing* that Regulation was arbitrary, capricious, and contrary to the relevant statute; and that the agency's action in *applying* the Regulation to Hospice Complete's cap refund determination for the fiscal year 2007 was arbitrary, capricious, and contrary to the relevant statute.

The court finds that Hospice Complete's motion for judgment on the merits is due to be granted as to the claims based on the cap determination for fiscal year 2007.

The court will enter a separate order consistent with this opinion, including a permanent injunction enjoining the Secretary from using 42 C.F.R. § 418.309(b)(1) to calculate Hospice Complete's cap refund determinations for hospice care for any past, present, or future accounting year and enjoining the Secretary from enforcing against Hospice Complete any cap refund determinations calculated using that Regulation, including but not limited to the cap refund determinations for fiscal year 2007. Further, the court will remand to HHS the claims asserted in 09-2398 based on fiscal year 2007 calculations and will order the PRRB to recalculate Hospice Complete's fiscal year 2007 cap refund determination in proper accordance with 42 U.S.C. § 1395f(i)(2).

The case will proceed in this court with the newly added claims involving the cap

determination for fiscal year 2009.

Dated this 3rd day of April, 2012, but entered *nunc pro tunc* effective as of the 30th day of March, 2011.

KAREN OWEN BOWDRE
UNITED STATES DISTRICT JUDGE